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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

HM12/0321

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DECLoux, A

ART UNIT

PAPER NUMBER

1644
DATE MAILED:

03/21/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/464,303

Applicant(s)

Stahl et al.

Examiner

DeCloud, Amy

Group Art Unit

1644



Responsive to communication(s) filed on _____

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1-41 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-41 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Restriction to one of the following inventions is required under 35 CFR121:

Group I, claims 1-6, drawn to a method for inhibiting LCP associated complement activation in vitro, classified in class 435, subclass 7.1,

Group II, claims 1, 2 and 7, drawn to a screening assay for inhibiting LCP associated complement activation, classified in class 435, 7.1

Group III, claims 1, 8-17, drawn to a method for inhibiting LCP associated complement activation comprising administration of an MBL inhibitor, classified in class 424, subclass 184.1,

Group IV, claims 18- 35, drawn to a composition comprising an MBL inhibitor, and a hybridoma cell line, classified in class 424, subclass 137.1, and class 514, subclass 2, and class 435, subclass 329, or

Group V, claims 36-41, drawn to a method for screening a cell for susceptibility to treatment with an MBL inhibitor, classified in class 435, subclass 7.2.

It is noted that Claim 1 will be examined only to the extent of the elected subject matter within the elected group, and that group I will be examined only with respect to its in vitro embodiments.

2. Group IV and Groups I-III are related as a product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the composition comprising an MBL inhibitor can be used as an antigen in a method to make antibodies.

3. Groups I-III and V are unique methods. The methods of Groups I and III and the methods of Groups II and V differ with respect to their endpoints because groups II

and VIII encompass screening assays while groups I and III encompass methods of inhibiting LCP associated complement activation. The methods of Groups II and V have different endpoints, since said method of group II screens for inhibition of LCP associated complement activation, while the method of Group V screens for susceptibility of a cell for susceptibility to treatment with an MBL inhibitor. The methods of Groups I and III differ with respect to their method steps since Group I will be examined with respect to *in vitro* method steps, and Group III will be examined with respect to the *in vivo* method steps associated with methods of administration. Therefore, Groups I-III and V are patentably distinct each from the other.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of the non patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

5. If Group I, II or III is elected, the applicant is further required under 35 U.S.C. 121:

A) To elect a method for inhibiting LCP associated complement activation that encompasses a **specific inhibitor of MBL**, such as an antibody or a MASP binding peptide, as recited in claims 4 and 6, respectively, or as recited in claims 12 and 13, respectively,

6. If Group III is elected, the applicant is further required;

To elect a method or for inhibiting LCP associated complement activation that is associated with a **specific disorder**, such as one recited in claims 14-15 and 17.

7. If Group IV is elected, the applicant is further required:

To elect a composition comprising a **specific inhibitor of MBL**, such as an antibody or a MASP binding peptide, as encompassed by claims 22 and 18, respectively.

If an antibody is selected, then applicant is further required to elect a **specific antibody**, such as one recited in claims 23, 24 or 25, and if disclosed, the **hybridoma cell line** that produces said antibody, such as one recited in claim 30, 31, or 32

8. If Group V is elected, the applicant is further required under 35 U.S.C. 121:
To elect a method for screening a cell for susceptibility to treatment with a

specific inhibitor of MBL, such as an antibody or a MASP binding peptide, as encompassed by claim 36.

9. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. The following claim(s) are generic: claims 1, 7, 8, 18, 33, and 36-41, for example

13. The species are distinct each from the other for the following reasons:

a. The recited inhibitors of MBL have different biochemical characteristics, structure and functions,

i. the recited antibodies have unique amino acid sequences and bind unique epitopes,

ii. The hybridoma cell lines differ from each other because they each secrete a unique antibody product

b. The recited disorders differ with respect to physical symptoms and etiology.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. A telephone call to request an oral election was not made due to the complexity of the restriction.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
March 21, 2001

Mary B. Tung
MARY BETH TUNG, PH.D
PATENT EXAMINER